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10/664,171	09/16/2003	Michi Garrison	13854.4002	3332

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ORRICK, HERRINGTON & SUTCLIFFE, LLP  
IP PROSECUTION DEPARTMENT  
4 PARK PLAZA  
SUITE 1600  
IRVINE, CA 92614-2558

EXAMINER

WITCZAK, CATHERINE

ART UNIT PAPER NUMBER

3767

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/664,171

Applicant(s)

GARRISON ET AL.

Examiner

Catherine N. Witczak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/3/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Simpson et al (US 6,126,635). In Figure 1, Simpson et al disclose a catheter (40) and a catheter/guidewire (12), each having a proximal and distal end. Both the catheter and catheter/guidewire have expandable occlusion devices associated therewith. Furthermore, Figure 1 discloses that the second occlusion device (20) is adapted to expand distally of the first occlusion device (48). Simpson et al also disclose that the catheter/guidewire is slidably housed within a first lumen in the catheter such that the distance between the first and second occlusion device may be varied in order to isolate an interior segment of a desired extent in column 2, lines 59-67.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 4, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al in view of Preissman et al (US 5728063).

  
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In regards to claims 1, 7 and 9, Simpson et al disclose in Figure 1 a first catheter (40) and a second catheter (12), each having a proximal and distal end. Both the first and second catheter have compliant expandable occlusion devices associated therewith. Furthermore, Figure 1 discloses that the second occlusion device (20) is adapted to expand distally of the first occlusion device (48) and is provided with an infusion port (column 3, lines 53-55). Simpson et al also disclose that the second catheter is slideably housed within a first lumen in the first catheter such that the distance between the first and second occlusion device may be varied in order to isolate an interior segment of a desired extent in column 2, lines 59-67.

In regards to claim 4, Simpson et al disclose in Figure 2 a second catheter (12) spaced from the inner wall of a first catheter (40), creating a coaxial lumen (52) surrounding a centrally located lumen (24).

Simpson et al disclose the claimed invention except for one of the catheters having a relatively stiff proximal region, a softer intermediate region and a still softer distal region. Preissman et al teach that it is known to use a relatively stiff proximal region, a softer intermediate region, and a still softer distal region in column 3, lines 17-31 to provide sufficient flexibility to permit access to tortuous regions while retaining sufficient tensile, column, and hoop strengths to enhance resistance to kinking and collapse (column 2, lines 2-6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Simpson et al with a catheter with a relatively stiff proximal region, a softer intermediate region and a still softer distal region as taught by Preissman, since such a modification would provide the system with a catheter having a relatively stiff proximal region, a softer intermediate region and a still softer distal region for providing sufficient flexibility to permit access to the tortuous regions while retaining sufficient tensile, column, and hoop strengths to enhance resistance to kinking and collapse.

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3. Claims 3 and 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Preissman et al as applied to claim 1 above, and further in view of Conway et al (US 6,102,929).

Simpson et al in view of Preissman et al disclose the claimed invention except for a pressure regulator and a pressure monitoring port. Conway et al teach that it is known to use a pressure regulator and monitoring port as set forth in column 11, lines 45-67 to provide the physician with the ability to control the pressure in the occlusion devices. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Simpson et al and modified by Preissman et al with a pressure regulator as taught by Conway et al, since such a modification would provide the system with a pressure regulator for providing the physician with the ability to control the pressure in the occlusion devices.

4. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preissman et al as applied to claim 1 above, and further in view of Baker et al (US 2002/0026217).

Simpson et al in view of Preissman et al disclose the claimed invention except for the second catheter having three lumens with the centrally located lumen provided with an axially extending tube. Baker et al teach that it is known to use a trilumen catheter with an axially extending tube disposed within the centrally located lumen as set forth in Figure 3 to provide a catheter with additional lumens which may be used for additional infusion devices or other purposes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Simpson et al and modified by Preissman et al with a trilumen catheter with an axially extending tube disposed with the centrally located lumen as taught by Baker et al, since such a modification would provide a catheter with additional lumens which could be used for additional infusion devices or other purposes.

***Response to Arguments***

5. Applicant's arguments, see Remarks, filed 5/3/2006, with respect to the IDS, specification, and claim objections have been fully considered and are persuasive. The objection of the IDS, specification and claims has been withdrawn.

6. Applicant's arguments filed 5/3/2006 have been fully considered but they are not persuasive.

In response to applicant's argument in regards to claim 2 that the catheter/guidewire (12) of the Simpson patent is not a guide wire as claimed in claim 2, upon reviewing the structural features of claim 2 and Figure 9 of the Applicant's application and Figure 1 of the Simpson patent, Examiner concludes that there is no structural features claimed or shown in the drawing of the Applicant's application that would distinguish what the applicant refers to as a guidewire and what the Examiner considers to be a catheter/guidewire in the Simpson patent. In light of this, Examiner maintains that the Simpson patent does disclose the catheter system as claimed in claim 2, since the Simpson patent meets all the structural limitations.

In response to applicant's argument in regard to claim 1 that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Preissman teaches that it is known to use a catheter of varying stiffness in order to provide a more easily maneuverable catheter. Seeing as the Simpson patent discloses a catheter for use in biological conduits, such as blood vessels

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(column 4, line 44-45), which include tortuous paths, it would be obvious to one of ordinary skill in the art to combine the two references so that the catheter as taught by Simpson could be more easily maneuvered through biological conduits by using a catheter of varying stiffness as taught by Preissman, since Preissman discloses that such a catheter would provide sufficient flexibility while maintaining sufficient tensile strength to be guide through tortuous regions.

In response to applicant's arguments in regards to claims 3-6, that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant argues that subject matter of the Conway and Baker patents is substantially different than that of the Simpson and Pressman patents. Examiner points out that all these patents relate to catheters, and thus combining these teachings would be in the scope of a person of ordinary skill in the art.

### *Conclusion*

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Witczak* 7/7/106

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*